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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,504	10/19/2001	Steven J. Siegel	PENN-0789	3358

7590 04/08/2005

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,504	SIEGEL ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear

AU 1615

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 01/13/05. Claims 1-10 are pending.

Specification

1. The objection to the disclosure for containing hyperlink and/or browser executable code is withdrawn in light of the amendment to the specification deleting the hyperlink. Examiner thanks applicants for amending the specification to remove the hyperlink.

Claim Rejections - 35 USC § 112

2. The rejection of claim 4 under 35 U.S.C. 112, first paragraph, because of the scope of enablement for all organic solvent is withdrawn in light of the amendment to the claims where the claims now recite acetone.

Claim Rejections - 35 USC § 102

3. Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kino et al. (WO 94/10982, cited in applicants' specification, English abstract).

Applicants argue that the depot formulation of Kino differs from the depot formulation of the instant claims because Kino does not prepare the formulation by either solvent casting or compression molding. Applicants also argue that in Kino, "the desired pharmacological effects upon injection of their microspheres can be obtained continuously in one injection per 1 to 8 weeks," while implants of the instant claims delivers steady state concentrations of haloperidol for five months or more.

4. Applicants' arguments filed 01/13/05 have been fully considered but they are not persuasive.

Applicants based their traversal of the rejection on US 5,871,778. However, US 5,871,778 is a divisional application of application serial number 08/443,021, now US 5,656,299, which is a continuation-in-part of PCT/JP93/01673, which is published as WO 94/10982. Since US 5,871,778 is a divisional of US 5,656,299, which is a CIP of WO 94/10982, the US 5,871,778 is not exactly the same as the WO reference. Instant claim 1 is directed to a formulation that comprises biodegradable polymer and haloperidol and the formulation can be implantable. The WO reference discloses a formulation that contains biodegradable polymer and haloperidol. EP 0 669 128 B1 is the same as PCT/JP93/01673 published as WO 94/10982. In the EP document, paragraph [0009] discloses that the formulation is sustained release and the concentration of the active agent in blood plasma is maintained at constant level by a single injection over a prolonged period of time. The sustained release formulation of Kino reads on steady state delivery. While the instant claim 1 recites "delivery system for delivery of steady state concentrations of haloperidol to a patient for 5 months or more," the instant claim 1 does not exclude the formulation of Kino that comprises the same biodegradable polymer and haloperidol so that extent that the Kino formulation can also deliver haloperidol to a patient for 5 months or longer and maintain a steady blood level of haloperidol. "For delivery of steady state concentrations of haloperidol to a patient for 5 months or more" is an intended use of the formulation. While Kino discloses an administration every 1 to 8 weeks, the instant claim does not specify the frequency of the administration and the prior art does not rule out that the blood level of haloperidol can be maintained by 1 injection per week

or 1 injection per 8 weeks. Also, since the instant composition and the composition of the prior art contain haloperidol and biodegradable polymer, both compositions would have the same property. How the formulation is prepared is important only when there is a structural difference between the formulations. In this case, there appears not to be a difference. Claims 1 and 2 are formulation/device claims and the process of formulating the devices is not critical. Thus solvent casting and compression molding is not critical to the device which is structurally/compositionally the same as that of the prior art. There is no persuasive presentation that of two formulations, both containing biodegradable polymer and haloperidol, one would be removable and the other not removable. Both contain polymers that are biodegradable. It is respectfully noted that removal of the device in the event the device exhibits unwanted side effects is an event is would/may occur in the future upon future determination.

5. Claims 1-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (J. controlled Release, 1988, 203-212, cited by applicants on form PTO 1449).

Applicants argue that the instant depot formulation is removable and that of Cheng is not removable. Furthermore, applicants argue that the solvent coated and compression molded device of the instant claim is designed to deliver steady state concentrations of haloperidol for five months or longer.

6. Applicants' arguments filed 01/13/05 have been fully considered but they are not persuasive.

Solvent molding and compression molding are processes/methods of fabricating the formulation and the claims are not method/process claims. And product-by-process claims are not limited to the manipulations of the recited steps; only the structure implied by the steps is

critical. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, if the instant device comprising haloperidol and biodegradable polymer is removable, then, the device of the prior art containing haloperidol and biodegradable polymer would be removable as well.

To be able to remove a device if and when unwanted side effect develops or is detected is in the future and the same would be true of a prior art device whose parts are biodegradable polymer and haloperidol. There is nothing in the instant device that would permit it to be removed in the future and since the device of the prior art contains the same parts as the instant device, its future removal is not forbidden or impossible. There is no persuasive presentation that of two formulations, both containing biodegradable polymer and haloperidol, one would be removable and the other not removable. Both contain polymers that are biodegradable. It is respectfully noted that removal of the device in the event the device exhibits unwanted side effects is an event is would/may occur in the future upon future determination.

7. Claims 1-6 remain rejected under 35 U.S.C. 102(e) as being anticipated by Brodbeck et al. (US 6,130,200).

Applicants traverse the rejection on the grounds that Brodbeck relates to a gel and the method of producing the gel differs from the method of producing the instant implant.

8. Applicants' arguments filed 01/13/05 have been fully considered but they are not persuasive.

The instant claims are directed to a device/formulation. An implant is not claimed. The claims direct that the formulation be implanted or the device be implantable. Thus the instant composition, which comprises a biodegradable polymer and haloperidol and implantable also implies that another composition comprising haloperidol and biodegradable polymer would be implantable. This is a future event; and there is no persuasive presentation that of two formulations, both containing biodegradable polymer and haloperidol, one would be implantable and the other not. Both contain polymers that are biodegradable. It is respectfully noted that the instant claims do not exclude a gel formulation and gels are not excluded from being implantable.

Claim Rejections - 35 USC § 103

9. Claims 4-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (J. Controlled Release, 1988, 203-212, cited by applicants on form PTO 1449).

Applicants argue that Cheng does not disclose solvent casting the haloperidol and biodegradable polymer to produce completely dry haloperidol-polymer material and that Cheng does not disclose all the limitations.

10. Applicants' arguments filed 01/13/05 have been fully considered but they are not persuasive.

Cheng freeze dries, and freeze drying takes place under pressure and the application of the pressure and the evaporation of the solvent results in solid product, which the compression in

the instant claims would lead to. Since Cheng discloses that the formulation is implantable, would indicate that the product would be made into a form that is suitable for implantation.

11. Claims 7-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brodbeck et al. (US 6,130,200).

Applicants argue that the product of Brodbeck is not produced by solvent casting and compression molding and that Brodbeck does not disclose device that delivers steady state concentrations for 5 months or longer and Brodbeck therefore, fails to teach all the "requisite limitations and further fails to provide reasonable expectation of success with respect to the claimed invention.

12. Applicants' arguments filed –1/13/05 have been fully considered but they are not persuasive.

Claims 7-10 depend from claim 1 directly or indirectly and therefore, the process of solvent casting and compression molding is not critical. Solvent molding and compression molding are processes/methods of fabricating the formulation and the claims are not method/process claims. And product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps is critical. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, if the

instant device comprising haloperidol and biodegradable polymer is removable, then, the device of the prior art containing haloperidol and biodegradable polymer would be removable as well.

To be able to remove a device if and when unwanted side effect develops or is detected is in the future and the same would be true of a prior art device whose parts are biodegradable polymer and haloperidol. There is nothing in the instant device that would permit it to be removed in the future and since the device of the prior art contains the same parts as the instant device, its future removal is not forbidden or impossible. There is no persuasive presentation that of two formulations, both containing biodegradable polymer and haloperidol, one would be removable and the other not removable. Both contain polymers that are biodegradable. It is respectfully noted that removal of the device in the event the device exhibits unwanted side effects is an event is would/may occur in the future upon future determination.

No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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James M. Spear

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